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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

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| EXAMINER |
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FUBARA, BLESSING M

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| ART UNIT | PAPER NUMBER |
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1618

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08/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/757,433

Applicant(s)

ULBRICHT ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-14,30 and 45-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14,30 and 45-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Examiner acknowledges receipt of English Translation of the Foreign priority document DE 101 26 501.8. Claims 3-6 are canceled. Claims 45-51 are added. Claims 8-14, 30 and 45-51 are pending.

### ***Response to Arguments***

**Previous rejections that are not reiterated herein are withdrawn.**

### **Priority Document**

The declaration filed with the application on 1/15/2004 lists the DE priority document as 101 26 501.8-41 while the document translated is DE 101 26 501.8. Applicant is requested to clarify the difference in the numbers.

**Applicant's Issue** with the office action citing paragraphs from the published application is noted. However, the contents of the published application and the filed application are the same even though the number of digits in the numbering of the paragraphs may differ. Applicant has also not indicated that the contents of the published application and the originally filed application are not the same.

### ***Regarding the Amendment to the specification***

1. The amendment filed 09/20/05 remain objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not

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supported by the original disclosure is as follows: Deletion or removal of “one or more” from paragraphs 10 and 22 of the specification introduces new matter to the disclosure. The specification as originally filed does not support deleting/removing “one or more” that identifies the extent of the nonvolatile constituents. The specification as originally filed does not state that the nonvolatile constituents are urea and hydrophilic polymer; specifically, paragraph 23 states “the amounts of urea are in each case based on the **nonvolatile constituents** of the use according to the invention and can be from 35 to 85 percent by weight, from 39 percent by weight to 83 percent by weight, from 46 percent by weight to 63 percent by weight, or from 55 percent by weight to 63 percent by weight.”

Applicant is required to cancel the new matter in the reply to this Office Action.

*Response to Arguments*

2. Applicant's arguments filed 6/05/07 have been fully considered but they are not persuasive.

Applicant argues that the removal of the “one or more” by amendment to the specification filed 9/20/05 simply rephrases paragraph [010] from

- a) one or more nonvolatile constituents,
- b) urea in an amount . . . , relative to the nonvolatile constituents of the preparation,
- c) a hydrophilic film-forming agent and
- d) water or an alcohol-water mixture

to

- a) nonvolatile constituents, which comprise urea in an amount . . . , relative to the nonvolatile constituents of the preparation, and a hydrophilic film-forming agent; and
- b) water or an alcohol-water mixture.

, which applicant says that is supported

by the MPEP 2163.07(a) and as such should not be held new matter. Applicant further

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states that support for urea as non-volatile constituents is provided by paragraphs [001], [007], [008] and [018], also paragraphs [010], [022] and [036]; so that the amendment to the specification is not new matter.

**Response:**

The proposed amendment to the specification deleting a) and c) from paragraphs [010] and [022] is new matter which was not envisioned.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The boundaries of “larger” in the amount of urea that is larger than the amount of water is not clear/not known.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 9-12, 30 and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugler et al. (GB 2 202 743).

Laugler in GB 2 202 743 discloses treating fungal infections of nails and surrounding tissues (page 5, 3<sup>rd</sup> full paragraph) by administering composition in the form of a lotion or gel or vanish (page 2, 4<sup>th</sup> full paragraph), the composition comprises in the dissolved state miconazole or econazole in amount of from 1-2% by weight relative to the total weight of the composition (page 2, 3<sup>rd</sup> full paragraph and last paragraph), urea in amount of from 1 to 20% relative to the total weight of the composition (page 3, first full paragraph), dissolving intermediary (solvent) and film forming resin (paragraphs 2-5 of page 3), 0.5 to 2% and preferred amount of 0.7-1.5% gelling or thickening agents in the case of gels (page 3, last paragraph to page 4, 1<sup>st</sup> full paragraph), and film forming resin such as polyvinylpyrrolidone/vinyl acetate polymer for varnishes (page 4, 2<sup>nd</sup> full paragraph) with the film forming resin present at from 7.5 to 30%, preferably from 10-20% relative to the total weight of the composition (page 5, 1<sup>st</sup> full paragraph). Varnish meets the limitation of a solution or liquid as recited in claim 30, since

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varnish can be a liquid or solution and the prior art does not define the varnish as other than a liquid or solution. The film forming resin such as polyvinylpyrrolidone/vinyl acetate polymer and present in an amount of 7.5 to 50% meets the limitation of hydrophilic film forming agent of claims 30, 8 and 49. The presence of alcohol and water in the composition of Laugler, for example, the varnish preparations in examples I and IV contain both water and ethanol meeting the requirements of the amended claim 30 as an aqueous solution and claims 9 and 10 for containing ethanol. In Examples I and IV, the ratio of the alcohol to water is at about 2.6:1 and 6.4:1 respectively and meeting requirements of claims 11 and 12. The amount of the water and alcohol, that is the aqueous alcoholic mixture, in Example I is 35% meeting the limitations of new claims 45 and 46; regarding new claims 47 and 48, the prior art teaches that water can be present at a range of from 5-20% (page 3 at lines 1 and 2) such that the amount of the water is optimizable by the artisan to produce a varnish preparation that would hydrate the nail since Laugler discloses that the composition when applied hydrates the nail (page 2, first full paragraph).

Laugler discloses the aqueous solution of the claims as described above. The percent amount of urea taught by Laugler at 1-20% overlaps the claimed range in claim 30 parts of the disclosed range touches parts of the claimed range. The claimed range would have been obvious because the points within the disclosed range that touches points within the claimed range renders obvious the claimed range such that the artisan following the teachings of Laugler would have prepared composition with any of the amounts of urea that renders obvious the claimed composition. There is no demonstration that the claimed range of urea provides unexpected results to the claimed composition.

8. Claims 8, 13, 14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugler et al. (GB 2 202 743) in view of Crandall (US 5,639,740).

Laugler is described above as rendering claims 9-12, 30 and 45-49.

Crandall discloses method of treating skin, hair, cracked toenails, cracked fingernails, hooves and horns of humans and animals (abstract; column 3, lines 43-45) with moisturizing composition that comprises lecithin, isopropyl palmitate, water, PLURONICS, urea or ceramide or salicylic acid or hyaluronic acid, various alpha hydroxyl-compounds such as lactic acid, citric acid and glycolic acid, gelling agents such as polyvinylpyrrolidone, polyvinyl alcohol and poloxamers (column 4, lines 56-60; column 5, lines 22-28 and 42-51), and stabilizers, antioxidants, preservatives, humectants, antimicrobial agents (column 5, lines 67 to column 6, line 7). The lactic acid meets claim 13. Thus, Crandall is relied upon for disclosing method of treating cracked fingernail or toenail with a spray composition, which is a liquid, that can contain lactic acid or citric acid and the lactic acid is present at amounts of 0.01% to 1% meeting claim 14; the inclusion of the lactic acid may further aid in moisturizing keratinous materials according to Crandall (column 5, lines 13-31). Both the composition of Laugler and Crandall are used for the same purpose of hydrating/moisturizing brittle or cracked nails.

Laugler teaches treating fungal infections of nails by topically applying composition containing urea and film-forming polymer to the affected areas, Laugler does not teach polyvinylpyrrolidone as the film-forming polymer in the composition. Since Crandall uses a composition containing urea and polyvinylpyrrolidone film-forming polymer to treat cracked fingernails, one film-forming polymer can be used in place of another film-forming agent and



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expect to effectively treat cracked or infected nail.. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the formulation of Laugler to treat fungal infected nail. One having ordinary skill in the art would have been motivated to modify the formulation of Laugler as suggested by Crandall with the expectation that the modified composition would be effective in treating infected nails.

9. Claims 30 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugler et al. (GB 2 202 743).

Laugler renders obvious the method of claim 30 as described above. Laugler's formulation contains 1-20% urea, while new claim 50 requires between 25 and 33 percent urea. There is no provision in applicant's specification that the range of urea recited in claim 50 provides unusual results to the method of claim 30. However, the disclosure of range of amount of urea that can be used in the treatment suggests that amounts can be adjusted to provide the desired effect. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the composition of Laugler. One having ordinary skill in the art would have been motivated to adjust the amount of urea to obtain desired level of treatment of fungal infection (onychomycosis).

### ***Response to Arguments***

10. Applicant's arguments filed 6/05/07 as the arguments apply to the new rejections have been fully considered but they are not persuasive.

Applicant argues that Laugler does not teach or suggest method of hydrating brittle toenails or finger nails but rather teaches "treatment of fungal infections of the nails or

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surrounding tissues,” so that Laugler does not inherently or explicitly refer to applying the preparation to brittle toenails or fingernails. b) That Laugler discloses broad amount of 7.5% to 30%, preferably 10-20% of film-forming polymers relative to the total weight of the composition, and “does not teach or suggest a solution having film forming agent present in amount of from 15-35% by weight based on the entire solution” as is now recited in the amended claim. c) Laugler uses 10% urea in Example IV and broadly discloses urea in amounts of from 1-20% relative to the total weight of the composition. d) That Murdan is removed as art by the filing of the translation of the German priority reference. e) That Crandall does not suggest increasing the amount of urea; that the urea in Crandall is optional and is intended to be delivered to the skin, while the intended use of urea in Laugler is as a solubilizer for miconazole nitrate and econazole nitrate differing from the intended use of urea in Crandall. f) That the weight of urea in Laugler is not to exceed the weight of water.

**Response:**

It is brought to applicant's attention that although the prior art used in the present rejections is the same, the rejections are different in view of applicant's current amendment.

Regarding f), new claim 51 is not rejected over Laugler mooted the argument presented in f. Regarding d), the Murdan reference is dropped from the rejections.

Regarding a), it is known in the art that fungal infection (onychomycosis) of the nail leads to fragile or brittle nails. Thus, Laugler inherently applies the formulation to brittle toenails when Laugler applies the composition to fungal infected toenails. Regarding b), a percent spread of 22 percentage points in the prior art is not that broader than a 20 percentage spread in the claims and specifically claim 30. The “broad” range of polymer, 7.5 to 30% or

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preferred 10-20%, in the prior art overlaps the recited polymer range of 15-35 in amended claim 30. The effect is that polymer points within the disclosed range of the prior art touches points within the recited range and the recited range is therefore rendered obvious by the disclosed range of the prior art. Regarding c), applicant admits that Laugler discloses a amount of urea at 1-20% relative to the total weight of the formulation, and this amount overlaps the recited amounts of 15-35% (currently amended claim 30); and points within Laugler's range touches points within the recited range such that the recited range in the amounts of the polymer is rendered obvious by the prior art. Since the claims are amended to recite 15% to 35 % for the urea and polymer, and since the prior art discloses urea at 1-20%, which lies outside and within the recited range, Crandall is not used to provide a teaching of using amounts of urea that may be higher than 35% of the claims, therefore argument e) is rendered moot by the amendment and by the rejections adjusted to accommodate the current amendment to the claims.

No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

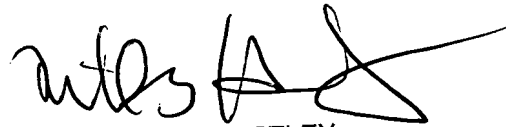
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

BF

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER